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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/ Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/ Counterclaim-Plaintiff.

Case No.: 3:21-cv-03496-VC

INTUITIVE SURGICAL INC.'S MOTION TO EXCLUDE TESTIMONY OF PHILIP J. PHILLIPS

Hearing Date: June 8, 2023
Hearing Time: 1:00 p.m.
Hearing Place: Courtroom 4

Judge: The Honorable Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 PM, or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA, 94102, Defendant-Counterclaimant Intuitive Surgical, Inc. will and hereby does move for an order excluding the opinions of Philip J. Phillips, proffered as an expert witness for Plaintiff Surgical Instrument Service Company, Inc.

This Motion is based on this Notice of Motion and Memorandum of Points and Authorities, the accompanying Declaration of Andrew Lazerow and attached exhibits, any reply or other supplemental briefing and/or evidence submitted by Intuitive, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUE

Defendant-Counterclaimant Intuitive Surgical, Inc. ("Intuitive") respectfully submits this motion pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude the opinions of Philip J. Phillips ("Phillips"). Plaintiff Surgical Instrument Service Corporation ("SIS") retained Phillips to opine on "the reasonableness of SIS's efforts to conform with all applicable FDA regulatory requirements in regard to servicing Intuitive Surgical's EndoWrists."[1] Lazerow Dec. Ex. 1 ¶ 1. Intuitive moves to exclude all of his opinions, *i.e.*, that:

1. "SIS acted reasonably in its effort to conform with FDA medical device requirements," *id.* ¶ 4;

2. "SIS is not a remanufacturer, as that term is defined by FDA," *id.* at Conclusion;

3. "the submission of a 510(k) and an FDA clearance by others does not establish that either is in fact, necessary or required for SIS's repair services," *id.* ¶ 4(iii); and

[1] Intuitive reserves the right to raise additional objections to Phillips's testimony at a later date. This motion focuses on issues fit for resolution at this stage of the case.

4. "Intuitive Surgical's customer communications alleged in SIS's Complaint and court filings are simply false and misleading," *id.* ¶ 4(iv).

None of these opinions withstands scrutiny under Rule 702. The first opinion is irrelevant and unreliable. One of the key issues in this case is whether modifying a limited-use EndoWrist to reset its use counter constitutes "remanufacturing" under FDA regulations, such that agency clearance is required. Whether SIS acted "reasonably" or not has no bearing on that question. Phillips' opinion is also unreliable because Phillips admitted at his deposition that he does not even ***know*** what efforts, if any, SIS undertook to conform to FDA requirements. He did not review a single SIS document or read a single SIS deposition before submitting his report. And he chose not to raise the subject in an interview he conducted with SIS's CEO. Without having any idea what SIS did to understand or comply with FDA regulations, Phillips has no basis to opine on whether that conduct was reasonable.

Phillips' second opinion – that SIS "is not a remanufacturer" under FDA regulations – is an inadmissible legal opinion and, in any event, demonstrably unreliable. Phillips has substituted his view of the FDA's legal regime for that of the agency itself. Phillips does not explain why he is uniquely able to discern SIS's regulatory status. He simply asserts, in a feat of *ipse dixit* conceit, that his opinion is absolutely correct. In the process of forming that opinion, Phillips did not even review, much less consider, the numerous statements by FDA officials and actions of the FDA that compel a contrary conclusion. He does nothing – other than posit that there is a "chance" they are all wrong – to square his opinion with the diametrically opposed views of every single FDA official who addressed the issue.

Phillips' third opinion – that a third party's submission, and FDA's clearance, of a 510(k) application for a remanufactured EndoWrist with a reset use counter does not establish that SIS was required to seek FDA clearance for the same activity – is an unhelpful and unreliable legal opinion. The opinion purports to resolve a legal issue within the province of the FDA and the Court, not the jury. Moreover, Phillips admits he does not know "details of the activity" Iconocare performed or that FDA assessed. Had he reviewed the documents, he would know that FDA repeatedly referred to Iconocare's

activities in modifying EndoWrists to reset their use counters as "remanufacturing" – exactly as the agency has characterized such activity every time it has been faced with the question.

Phillips' final opinion – that Intuitive's "customer communications" were false and misleading – could not be less reliable. Phillips derived his understanding of Intuitive's communications solely by looking at snippets in SIS's complaint and motion to dismiss opposition, not the complete communications. Yet at his deposition, Phillips admitted that he would want to see the "complete context" before he could conclude that a particular statement is false or misleading. And Phillips then contradicted his own report by admitting that at least one of the snippets he cited was truthful. Moreover, Phillips' assertion that Intuitive's alleged statements about SIS's need for FDA clearance were false cannot be squared with Phillips' belief that there is great "uncertainty" and "ambiguity" about FDA regulations on that subject. If, as Phillips maintains, "reasonable people" and "regulatory affairs professionals" regularly disagree about whether modifying EndoWrists to extending their programmed uses requires FDA clearance, then Phillips cannot reliably conclude that it was objectively unreasonable for Intuitive to share with customers its view (with which FDA agrees) that clearance is needed.

In fact, there was, and is, no genuine basis for uncertainty in the face of FDA's consistent statements on the issue, which confirm that Intuitive's statements were completely accurate. Phillips' deliberate choice simply to ignore FDA's consistent position renders all of his opinions on the subject inadmissible.

II. STATEMENT OF FACTS

Phillips has been an independent regulatory consultant since 2005. Lazerow Dec. Ex. 1 ¶ 12. From 1981 to 2005, he worked at the FDA Center for Devices and Radiological Health ("CDRH"). *Id.* ¶¶ 7, 9. During that time, Phillips was involved in the FDA's evaluation of premarket clearance applications for medical devices in the United States. *Id.* ¶¶ 10–11. Phillips gained familiarity with the "510(k)" regulatory clearance pathway. *Id*. He knows that the FDA makes regulatory classifications and clearance decisions based on the actions a company performs on a medical device, not based on the

company's intent or whether it owns the particular device under evaluation. *Id.* Ex. 2 at 396:8–397:11. He also knows that any company that makes a "significant change" to an existing device qualifies as a "remanufacturer" under FDA regulations and must seek clearance from the FDA before marketing such a device in the United States. *Id.* at 91:3–92:11.

SIS retained Phillips to offer four opinions in this matter:

Reasonability of SIS's Conduct and Beliefs. Phillips opines that "SIS acted reasonably in its effort to conform with FDA medical device requirements" and it "was reasonable" to conclude that "its commercial activities did not constitute 'remanufacturing' as defined by the Quality System Regulation." *Id.*, Ex. 1 ¶ 4. Phillips formed his opinions about SIS's efforts and beliefs in a vacuum. Phillips admitted that he "***did not know*** what efforts, if any, SIS had taken to conform to applicable regulatory requirements." *Id.* Ex. 2 at 224:17–22 (emphasis added). Phillips had not reviewed ***any*** of the more than 116,500 documents SIS produced in this case. *Id.* Ex. 1 at Exhibit 1. Nor had he reviewed the individual or 30(b)(6) depositions of SIS's CEO/President (Greg Posdal) and Executive Vice President (Keith Johnson). *Id*.

Nowhere in Phillips' reports does he cite any contemporaneous analysis that SIS performed about applicable regulatory requirements. Had he reviewed SIS's depositions, Phillips would have learned that, in fact, SIS took no "independent steps to ensure that the EndoWrist reset process complies with FDA regulatory requirements." *Id.* Ex. 3 at 61:20–24; *see also id.* at 46:12–15 ("Q: So SIS did not independently consider whether regulatory clearance was necessary to market the EndoWrist in -- EndoWrist reset process? A: Correct.").

Notwithstanding the discovery record available to him, Phillips chose to rely entirely on a 30-45 minute "interview" of SIS's President/CEO, Greg Posdal, for his knowledge about SIS's activities. *Id.* Ex. 1 ¶¶ 75–92; *id.* Ex. 2 at 220:15–25. But Phillips did not ask Mr. Posdal about the efforts SIS undertook to ensure that its actions complied with FDA regulations, because "that really wasn't an

interest of" his. *Id.* Ex. 2 at 223:21–224:19.[2] In that "interview," Mr. Posdal purportedly indicated that "SIS had no ***intent*** to do anything other than restore the performance of used EndoWrist instruments to the acceptable level of performance." *Id.* Ex. 1 ¶ 100 (emphasis added). But Phillips did not learn anything about how SIS's "intent" related to what SIS was actually doing with EndoWrists or the applicable FDA regulatory requirements. *Id.* ¶¶ 76–92. And Phillips acknowledged at his deposition that a company's ***intent*** has no impact on whether that company's actual activities constitute "remanufacturing" under FDA regulations. *Id.* Ex. 2 at 396:8–397:11.[3]

SIS as a Remanufacturer. Phillips opines that "SIS is not a remanufacturer as, that term is defined by FDA." *Id.* Ex. 1 at Conclusion. FDA regulations define a "remanufacturer" as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." 21 CFR § 820.3(w). A remanufacturer must obtain 510(k) clearance from the FDA before marketing a remanufactured device. Lazerow Dec. Ex. 2 at 91:3–92:11. Phillips believes that "reasonable people" can disagree about what qualifies as remanufacturing. *Id.* Ex. 1 ¶ 66 ("what changes to devices rise to a level of significance that constitutes 'remanufacturing' lies in the fact that reasonable people disagree with what is 'significant'"). Yet in this case, Phillips has "zero doubt" that he is correct that SIS was not engaged in remanufacturing. *Id.* Ex. 2 at 259:25–260:16, 409:10–20.

Phillips did nothing to determine whether the FDA had addressed the specific question at issue in this case: whether modifying an EndoWrist to extend the usage counter constitutes remanufacturing. Phillips did not review any of numerous statements by FDA officials on that specific point before

[2] Phillips learned about the modifications that SIS effected on EndoWrists through Mr. Posdal's endorsement of an expert report that describes a process developed by SIS's business partner, Rebotix, to modify EndoWrists with a reset use counter. Lazerow Dec. Ex. 1 ¶¶ 90, 93. Phillips does not explain how (if at all) the expert reports he cited affect his opinions. He also does not explain why he relied on the report of Joshua Sharlin when the party that proffered that report, Rebotix Repair LLC, withdrew it. *See id.* Ex. 6 at 12.

[3] Phillips felt that a company's views might be pertinent to an FDA enforcement action. Lazerow Dec. Ex. 2 at 259:25–260:16.

forming his opinions, even though he admitted at his deposition that he would want to consider those statements. *Id.* Ex. 2 at 27:14–25, 223:21–224:22. Had he reviewed the record in this case, Phillips would have learned that every pertinent statement by an FDA official (or related action by the FDA) confirms that the FDA views the activity of modifying EndoWrists to extend the number of uses as remanufacturing requiring FDA clearance. *See* § III(B), *infra*. And when asked to assume at his deposition that every single FDA official who has communicated with anyone in industry stated that the activity is remanufacturing, Phillips offered only that "there's a chance that the individuals could be wrong." Lazerow Dec. Ex. 2 at 158:13–159:24. Phillips conceded that he has not seen a single statement by anyone at FDA that agrees with him that the activity at issue in this case does ***not*** constitute remanufacturing. *Id.* at 47:10-24.

Significance of 510(k) Clearance Sought and Obtained by Another Remanufacturer. Phillips opines that "the submission of a 510(k) and an FDA clearance by others does not establish that either is in fact, necessary or required for SIS's repair [sic] services." *Id.* Ex. 1 ¶ 4(iii). Again, Phillips reaches this conclusion by ignoring the record of FDA's statements and actions, including the agency's extensive work in reviewing the Iconocare application (with no suggestion from the agency that such effort was unnecessary) and statements the FDA made about it. Nowhere did anyone from FDA tell Iconocare that its 510(k) application was unnecessary or not required.

Phillips also did not consider (or even know about) the fact that, in conjunction with clearance of Iconocare's 510(k) for remanufacturing a Si EndoWrist, the FDA created a new "product code" for a "computer controlled instrument" that has been "remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer." *Id.* Ex. 4 at ¶ 151 & fig. 3; *id.* Ex. 2 at 71:10–14. The FDA's product code indicates that the submission type is 510(k). *Id.* Ex. 4 at ¶ 151. Phillips admitted that he had not seen the new product code for remanufactured EndoWrists when he wrote his report. *Id.* Ex. 2 at 36:15–21. Phillips was also not aware of FDA guidance indicating that the creation of a product code means that "the proposed device differs significantly from the predicate

device with respect to technology, intended use or indications." *Id.* Ex. 2 at 112:18–22, 114:12–17, 118:2–120:22. Ultimately, Phillips admitted that he does not know whether Iconocare's activity constitutes remanufacturing because he has not seen the content of its 510(k) application. *Id.* at 46:23–47:5.

Intuitive Communications to Customers. Phillips opines that "Intuitive Surgical's customer communications alleged in SIS's Complaint and court filings are simply false and misleading." *Id.* Ex. 1 ¶ 4(iv). Phillips evaluated Intuitive's communications "based upon SIS's statements in its Complaint filed in this case and statements SIS has made in filings presented to the Court." *Id.* ¶ 75. He did not see, or ask to see, any actual communications by Intuitive. *Id.* Ex. 2 at 398:25–399:5, 400:12–401:5. He admitted that one of the statements attributed to Intuitive in his report – "the hospital has no way to know whether [a] refurbished instrument meets the rigorous specifications" of Intuitive and the FDA – was actually "a truthful statement." *Id.* at 418:18–419:2. Most of the allegations cited by Phillips are not Intuitive's communications but SIS's characterization of communications. *See id.* Ex. 1 ¶ 99 (quoting ¶¶ 97–98, 123–125 of SIS complaint); *Id.* Ex. 2 at 413:10–414:16, 422:8–15. And most importantly, Phillips admitted in his deposition that he could ***not*** conclude that the "snippets" of communications he reviewed in SIS's pleadings were false and misleading because he would "want to see the complete context." *Id.* Ex. 2 at 417:3–418:17.

III. ARGUMENT

The Federal Rules of Evidence permit qualified experts to offer only opinions that are (a) helpful to the jury, (b) based on sufficient facts or data, and (c) the product of reliable principles and methods (d) reliably applied to the facts of the case. Fed. R. Evid. 702. The party proffering expert testimony has the burden of showing the testimony is admissible by a preponderance of the evidence. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n.10 (1993). Proffered expert opinions are properly excluded if unreliable, such as where an expert summarily rejects unfavorable data in favor of information supporting his opinion. *See In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab.*

Litig., 524 F. Supp. 2d 1166, 1176–77 (N.D. Cal. 2007). Opinions not adequately explained must be excluded, too, because without adequate explanation the court cannot determine whether the expert's methods are reliable. *United States v. Hermanek*, 289 F.3d 1076, 1094 (9th Cir. 2002); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

A. Phillips' Opinion Regarding SIS's Efforts and Beliefs about Applicable Regulatory Requirements Is Irrelevant and Unreliable.

Phillips' opinion that SIS acted reasonably in its effort to conform with applicable regulatory requirements is irrelevant and unreliable. Despite his decades working as an FDA regulatory professional, Phillips proffers nothing to suggest that SIS's efforts or beliefs have any impact on the regulatory status of SIS's activities. To the contrary, Phillips confirmed that the FDA bases regulatory determinations on the activities that a company performs on a device, not the company's "intent." Phillips' opinion simply does not "fit" with any issue the jury must decide. *See Daubert*, 509 U.S. at 591 ("Rule 702 further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' This condition goes primarily to relevance.").

Even if his opinion about SIS's efforts or beliefs could somehow relate to a pertinent inquiry in the case, SIS cannot show that Phillips' opinions are based on "sufficient facts or data" consistent with Rule of Evidence 702(b). Although Phillips purports to opine that SIS's efforts to conform to regulatory requirements were reasonable, he admits that he ***does not know*** what efforts SIS actually undertook to conform to those requirements and disclaimed "interest" in that topic, even though it is literally the stated reason for his retention and the subject matter of his principal opinion. *Compare* Lazerow Dec. Ex. 1 ¶¶ 1, 4, *with id* Ex. 2 at 223:21–224:22. In addition to his lack of knowledge about SIS's efforts, Phillips also does not explain how the specific modifications that SIS and Rebotix made to EndoWrists relate to the regulatory requirements. Phillips has thus offered the Court no basis to conclude that his

opinions about SIS's efforts or beliefs are reliable. *See Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *4 (expert knowledge "requires more than a subjective belief or an unsupported speculation" (citing *Daubert*, 509 U.S. at 593)).

B. Phillips' Opinion that SIS Is Not a Remanufacturer Is an Unreliable Legal Conclusion.

Phillips' opinion that SIS is not a remanufacturer is inadmissible for several reasons. *First*, and most fundamentally, the opinion is a legal conclusion. Phillips is offering to tell the jury how he thinks the FDA's legal regime applies to the facts of this case, substituting his own personal conclusions for those of the agency.[4] But "[a]n expert witness cannot give an opinion as to her *legal conclusion*, *i.e.*, an opinion on an ultimate issue of law." *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008) (emphasis original) (excluding opinion that "appl[ied] agency law to the facts of [the] case"); *see also Mannick v. Kaiser Found. Health Plan, Inc.*, 2006 WL 1626909, at *17 (N.D. Cal. June 9, 2006) (explaining that opinions "resolving doubtful questions of law" are not helpful to the fact-finder and invade the "exclusive province of the trial judge"); *Blair v. Shinseki*, 2015 WL 12743841, at *8 (C.D. Cal. Apr. 29, 2015), *aff'd*, 685 F. App'x 587 (9th Cir. 2017) (excluding "legal conclusion" testimony because "[i]nterpretation of . . . regulations and policies is a question for the Court"). As shown below, the evidence from the FDA makes it clear that the FDA has decided that modifying EndoWrists to extend the number of uses constitutes remanufacturing requiring FDA clearance.

[4] Intuitive accepts that, insofar as Plaintiffs' experts or other witnesses are not permitted to offer opinion testimony on legal issues, Intuitive's witnesses will not be permitted to do so either. Unlike Phillips, however, Intuitive's FDA expert, Christy Foreman, has applied her expertise in FDA policies, processes, and procedures to the objective evidence in the record in order to opine that ***the FDA*** has determined that modifying EndoWrists to reset their use counters is a remanufacturing activity that requires 510(k) clearance. *See* Lazerow Dec. Ex. 4 ¶ 16(b)(iii) ("Objective and publicly available evidence demonstrates that ***FDA*** has determined that removing or extending the usage limitation on EndoWrist instruments is a manufacturing activity, and as such, it requires 510(k) clearance.") (emphasis added). Unless the Court opens the door to experts offering legal opinions on these issues, Intuitive would not expect to offer any opinions by Foreman that go beyond explanations of the FDA's own decisions, which are offered to rebut the inadmissible legal opinions of Phillips.

However, even if FDA had not made that determination, it would still be the province of this Court – not an expert or the jury – to do so.

Faced with similar opinions, two courts in Florida excluded legal opinion testimony from other FDA experts on the regulatory status of companies engaged in modifying EndoWrists with reset use counters. The Court in *Rebotix Repair Inc. v. Intuitive Surgical, Inc.* ("*Rebotix*") ruled that two FDA experts could not give "ultimate legal opinion[s] as to Rebotix's compliance with regulatory requirements" or espouse their "own personal interpretations of relevant regulations ***to the extent they differ from the FDA's public interpretations***." Lazerow Dec. Ex. 6 at 8, 16 (emphasis added). Likewise, the Court in *Restore Repair Inc. v. Intuitive Surgical, Inc.* ("*Restore*") held that the "role of the Court is to determine the law regarding 510(k) clearance and instruct the jury what was required of Plaintiffs under the law." *Id.* Ex. 7 at 9. As in *Rebotix* and *Restore*, and consistent with Ninth Circuit law, Phillips's legal opinions should be excluded on this basis alone.

Second, Phillips' opinion violates Rule 702 because it is an *ipse dixit* conclusion not based on the facts of this case. *See Joiner*, 522 U.S. at 144. Phillips is adamant that the regulatory definition of "remanufacturer" is "not clear and cannot be used to consistently and reliability [sic] differentiate remanufacturing from servicing." Lazerow Dec. Ex. 5 at pt. II and ¶ 11; *id.* Ex. 2 at 401:12–24 ("[T]he facts of this case make it very clear that no one knows what constitutes remanufacturing versus servicing."). Yet Phillips is equally adamant that he is uniquely and "definitively" able to distinguish remanufacturing from servicing in this case; he says there is no "doubt in [his] mind whatsoever" that SIS is ***not*** a remanufacturer. *Id.* Ex. 2 at 409:4–20.

Phillips did not even consider, much less take account of, the extensive record that FDA has itself made on this subject:

- In June 2015, in response to a 510(k) application filed by Rebotix Repair in which Rebotix ***referred to itself as a remanufacturer*** and identified its devices as "re-manufactured EndoWrists," the FDA used the term "remanufacture" (or a version of it) ***84 times*** in a deficiency letter to Rebotix. *Id.* Exs. 8, 9.

- In June 2018, after a distributor for Rebotix asked the FDA why the agency insisted on 510(k) clearance for EndoWrists modified with reset use counters when they were simply "repairing" the devices, an FDA reviewer explained that resetting the device use counter is a change to "device specifications" that qualifies as remanufacturing and requires 510(k) clearance. *Id.* Ex. 10 at BPI000335.

- In February 2020, a biomedical engineer on FDA's Robotic Assisted Surgery Devices Team sent emails to Rebotix and a Rebotix distributor, Restore Robotics that, based on the information on their websites, the FDA believes "that a 510(k) is needed before you continue your operation." *Id.* Ex. 11 at Intuitive-00706024, Intuitive-00706038. The Robotic Assisted Surgery Devices Team later asked for an internal consult from an FDA consumer safety officer, who recommended that activities to extend the "life and function" of EndoWrists "significantly change the devices' intended use, constitute remanufacturing, and require premarket notification review to legally market." *Id*. at Intuitive-00706073.

- In November 2021, the FDA sent Rebotix an official regulatory letter stating that "[i]t has come to our attention that you may be remanufacturing the da Vinci S EndoWrist Instruments . . . in a manner that potentially violates the FD&C Act. . . . [Such] Instruments were cleared for a set number of uses. By extending the number of uses, your activities may be altering the intended use of the subject device." *Id.* Ex. 12 at REBOTIX175417.

- In a March 2022 deficiency letter to Iconocare, FDA made it clear that since Iconocare was seeking to extend the useful life of an EndoWrist beyond the 10 uses designed by Intuitive, "this change would be considered a change to device specifications," made it clear that Iconocare's device is "considered a remanufactured device," and directed Iconocare to include "Remanufactured by" and "Not Affiliated with Original Mfr." on the device housing. *Id.* Ex. 13 at AHP000534–35.

- In April 2022, a team lead on FDA's Robotic Assisted Surgery Devices Team sent an email to Rebotix that "the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k)/de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted. *Id.* Ex. 14 at REBOTIX175727. A policy analyst on FDA's compliance staff later reiterated that view to Rebotix in an email that also included the FDA Deputy Ombudsman and the Assistant Director of the Division of General Surgery Devices. *Id.* at REBOTIX175712.[5]

[5] Even after Intuitive's expert discussed many of these FDA statements in her report, Phillips still did not address any of them in his rebuttal report. Instead, at deposition, Phillips clung to the idea that statements by some of the individual FDA officials do not "necessarily represent the opinion of FDA." Lazerow Dec. Ex. 2 at 337:21–338:17. Phillips never defines what he views as the "opinion of FDA" or otherwise identifies the evidence he would want to see to ascertain the "opinion of FDA." In any event, (continued…)

Phillips also ignores the FDA's statements and actions vis-à-vis Intuitive. He attempts to support his opinion with reference to Intuitive's internal, nonpublic conclusion that, pursuant to FDA guidance applicable only to manufacturers (***not*** remanufacturers), Intuitive could extend the original number of uses for certain X/Xi EndoWrists by documenting the changes in its files and not seeking a new 510(k) clearance for those instruments. *Id.* Ex. 1 ¶¶ 105–111; *id.* Ex. 2 at 296:18–24, 302:13–303:16. But Phillips did not consider that when FDA learned that Intuitive had followed that regulatory pathway, FDA told Intuitive that it could not do so and instead needed to submit a new 510(k) because "by increasing the number of use and reprocessing cycles, the overall structural integrity of the device may be impacted after extended use." *Id.* Ex. 15 at Intuitive-02054181; *see also id.* Ex. 16 at Intuitive-00705779 ("we believe that changes to the reprocessing of your device require a 510(k)"). Phillips simply ignores this overwhelming body of evidence from the FDA that directly contradicts his opinion. Courts regularly exclude such expert testimony that "cherry-picks" supporting facts and ignores (or rejects) "the great weight of the evidence that contradicts [the] conclusion." *See Bextra*, 524 F. Supp. 2d at 1176.

C. Phillips' Opinion Regarding the Impact of Iconocare's 510(k) Clearance Is an Unreliable Legal Conclusion.

Phillips' opinion that Iconocare's 510(k) clearance does not require SIS to have 510(k) clearance should be excluded for two reasons. *First*, like Phillips' opinion about SIS's regulatory status, his opinion about Iconocare's status is a legal conclusion not helpful to the trier of fact. *See Nationwide*, 523 F.3d at 1058; *Mannick*, 2006 WL 1626909, at *17; *Blair*, 2015 WL 12743841, at *8. Indeed, Phillips refers to the question of whether Iconocare is a remanufacturer as a "legal or regulatory decision." Lazerow Dec. Ex. 1 ¶ 121. Phillips should be prohibited from giving an "ultimate legal opinion" about the regulatory status of Iconocare and espousing his "own personal interpretations of relevant regulations to the extent they differ from the FDA's public interpretations." *Id.* Ex. 6 at 8, 16.

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the consistent messages from numerous FDA officials and actions of FDA provide strong evidence that the FDA views modifying EndoWrists to circumvent its use counter constitutes remanufacturing.

Second, Phillips' opinion should be excluded because he lacks sufficient – or in fact any – information on which to base a reasonable opinion about the regulatory status of Iconocare's activities. He found it significant that Iconocare referred to itself as a "reprocessor" in its application, *see id.* Ex. 1 ¶ 121, but completely ignores that the ***FDA*** considered Iconocare's device "a remanufactured device" and directed Iconocare to include "Remanufactured by" Iconocare on the device housing. *Id.* Ex. 13 at AHP000534–35. Moreover, Phillips admits that he does not know "the actual contents of the Iconocare 510(k)" or "what Iconocare actually is doing or intended to do or what they described to the FDA." *Id.* Ex. 2 at 45:11–21, 46:8–12. He thus cannot compare SIS's activities with Iconocare's activities in order to reliably assess the significance of Iconocare's application and clearance. The Court should act as the "gatekeeper" to exclude exactly this sort of unfounded, unreliable evidence from the jury. *See Joiner*, 522 U.S. at 142.

D. Phillips' Opinion that Intuitive's Customer Communications Were False and Misleading Is Unreliable.

Phillips' opinion that Intuitive's customer communications were false and misleading is not based on facts or data, is not rooted in any identifiable "principle or method," and is not the result of principles or methods "reliably applied" to the "facts of the case." Fed. R. Evid. 702(b)–(d). Phillips did not review any of Intuitive's communications to hospitals, even though he admitted that he would need the complete context of any communication before he could conclude that any statement was false or misleading. Lazerow Dec. Ex. 2 at 398:25–399:5, 400:12–401:5, 417:3–418:17. And he admitted at deposition that at least one of the alleged statements he identifies in his report as false is actually ***truthful***. *Id.* at 418:18–420:3. Phillips' admissions alone render his opinions unreliable and of no help to the jury. *See, e.g.*, *State Farm Fire & Cas. Co. v. Electrolux Home Prod., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013) ("[A]n expert's proffered opinion that merely parrots information provided to her by a party is generally excluded.").

Phillips's opinion that Intuitive's communications were "false or misleading" is also unreliable because it is entirely inconsistent with his other opinions, and thus is not based on any identifiable "principle or method . . . reliably applied . . . to the facts of the case." *See* Fed. R. Evid. 702(c)–(d). As discussed above, although Phillips claims to be uniquely able to opine about the proper application of the FDA's definition of "remanufacturing," he insists throughout his reports and deposition that the line between "remanufacturing" and "servicing" is "not clear and cannot be used to consistently and reliability [sic] differentiate remanufacturing from servicing." *See, e.g.*, Lazerow Dec. Ex. 5 at pt. II and ¶ 11; *id.* Ex. 1 ¶¶ 60, 62; *id.* Ex. 2 at 401:12–24. When confronted with the numerous statements by FDA that contradicted his opinion (statements he had not considered in formulating that opinion), he simply suggested that perhaps all of those FDA officials were wrong. He claims that "reasonable people," including experienced FDA regulatory consultants, regularly disagree about the application of FDA's regulations to the activities at issue in this case. *Id.* Ex. 1 ¶ 64; *id.* Ex. 2 at 127:10–23, 402:6–15.

In light of his view about this uncertainty and "reasonable" disagreement, Phillips inexplicably opines both that SIS was "reasonable" ***not*** to seek FDA clearance, and that Intuitive was "objectively ***un***reasonable" to conclude that SIS required FDA clearance. *Id.* Ex. 1 ¶¶ 123, 125 (emphasis added). Phillips never explains the clear contradiction between his opinions. And without such an explanation, the Court cannot make the findings required to admit Phillips's opinions consistent with Rule 702. *See Loy v. Rehab Synergies, LLC*, 558 F. Supp. 3d 402, 408 (S.D. Tex. 2021) ("Expert opinions that are unsupported, self-contradicted, or assumptive are to be excluded.").

To be clear, Intuitive strongly disagrees that there is any "uncertainty" on the regulatory status of EndoWrists that have been modified to circumvent the use counter. But the certainty that does exist on this point again conflicts with Phillips' *ipse dixit* opinions. Phillips never wrestles with the fact that FDA has uniformly stated and taken actions consistent with the view that modifying EndoWrists to extend the number of uses constitutes remanufacturing that requires FDA clearance – clearance that SIS never sought, much less secured, and that Intuitive accurately and reasonably asserted was needed.

IV. CONCLUSION

For these reasons, the Court should grant this Motion and exclude Phillips opinions.

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